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| APPLICATION NO.                                  | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------|----------------------|---------------------|------------------|
| 10/018,637                                       | 06/07/2002      | Hachiro Seno         | TAIYO50.001APC      | 5195             |
| 20995  | 7590 07/28/2006 |                      | EXAMINER            |                  |
| KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET |                 |                      | THANH, LOAN H       |                  |
| FOURTEENTH FLOOR                                 |                 |                      | ART UNIT            | PAPER NUMBER     |
| IRVINE, CA                                       | 92614           |                      | 3763                |                  |

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary  |  | Application No.  | Applicant(s)   |  |  |  |  |
|--|--|--|--|--|--|--|--|
|  |  | 10/018,637   | SENO, HACHIRO  |  |  |  |  |
|  |  | Examiner   | Art Unit   |  |  |  |  |
|  |  | LoAn H. Thanh  | 3763   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |  |  |  |  |  |  |
| WHIC<br>- Exter<br>after<br>- If NO<br>- Failui<br>Any r   | CORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DAISIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing at patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATIO<br>36(a). In no event, however, may a reply be ting<br>rill apply and will expire SIX (6) MONTHS from<br>cause the application to become ABANDONE | N. mely filed the mailing date of this communication ED (35 U.S.C. § 133). |  |  |  |  |
| Status   |  |  |  |  |  |  |  |
| 1)⊠  | Responsive to communication(s) filed on 19 Ap  | <u>oril 2006</u> .   |  |  |  |  |  |
| 2a)⊠   | This action is <b>FINAL</b> . 2b) This action is non-final.  |  |  |  |  |  |  |
| 3)   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |  |  |  |  |  |
|  | closed in accordance with the practice under E   | x parte Quayle, 1935 C.D. 11, 4  | 53 O.G. 213.   |  |  |  |  |
| Dispositi  | on of Claims   |  |  |  |  |  |  |
| 5)□<br>6)⊠<br>7)□  | Claim(s) <u>1,3-7,9,10,13,15,17 and 21-24</u> is/are page 4a) Of the above claim(s) is/are withdray Claim(s) is/are allowed.  Claim(s) <u>1,3-7,9,10,13,15,17 and 21-24</u> is/are page 15.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or  | vn from consideration.   |  |  |  |  |  |
| Applicati  | on Papers  |  |  |  |  |  |  |
| _  | The specification is objected to by the Examine  | r  |  |  |  |  |  |
|  | 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |  |  |  |  |  |  |
|  | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |  |  |  |  |  |
| 44)[7]   | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |  |  |  |  |  |
| 11)  | The oath or declaration is objected to by the Ex   | aminer. Note the attached Office   | Action or form PTO-152.  |  |  |  |  |
| Priority u   | nder 35 U.S.C. § 119   |  |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |  |  |  |  |  |  |  |
| Attachmen  | t(s)<br>e of References Cited (PTO-892)  | A) 🗖 Into-dam Surress  | v (PTO 413)  |  |  |  |  |
| 2) Notic 3) Inform   | e of References Cited (PTO-692) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date 06/20/06.   | 4)  Interview Summan<br>Paper No(s)/Mail D<br>5)  Notice of Informal<br>6)  Other:   |  |  |  |  |  |

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### **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,4-7,9,15, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarger (U.S. Patent No. 5,360,414) in view of Bellino (WO 92/04071).

Yarger discloses catheter having a tip end portion and a projection portion wherein the tip end portion comprises a plurality of side holes (28a-d) and having a groove 32,26 corresponding to the row for draining. Yarger discloses the width of the grooves to be between 0.1 mm to 1.0 mm to prevent significant occlusion of the grooves by debris or living tissue during drainage of a body cavity, viscous or wound. Yarger specifically discloses the through hole rows/ groove 26, 32 to be more narrow that the through holes (28) in order to provide fluid flow and prevent occlusion of grooves. See figures 1-10. See bridging paragraph starting on col. 2-3. col. 2, lines 30-36, col. 4 lines 64-col. 8, lines 57. Thus, as reasoned above, Yarger discloses the invention as substantially claimed. However, Yarger is silent to the specific depth of the grooves being 0.8 mm to 1.0 mm or the bottom surface of the single-pipe tube is 0.45 mm to 0.5 mm and the groove being more narrower at the inner portion than at the opening.

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Yarger does disclose that modifications and variations of the invention are well within the scope of the one of ordinary skill in the art. Thus, it would have been obvious to one of ordinary skill in the art to modify the depth of the groove as claimed as a mere design choice lacking any criticality of size as being merely preferable for the intended flow passage for draining the area where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device,

With respect to the groove being more narrow at the inner portion than at the opening, Billino discloses a tapered shape groove (see fig.1-2) for draining. It would have been an obvious design choice to modify the groove of Yarger with teachings of Billino as a mere design choice.

the claimed device was not patentably distinct from the prior art.

Claims 3,10,13,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarger (U.S. Patent No. 5,360,414) in view of Billino (WO 92/04071) and further in view of Hideki et al. (JP 08-266616).

Yarger discloses the invention as substantially claimed. See above. However Yarger does not disclose a cuff for securement to the body. Hideki et al. disclose a catheter having a tip end portion and a projection portion wherein the tip end portion comprises a plurality of side holes and having a groove corresponding to the row for draining in the analogous art. Hideki et al. further disclose cuffs as elements 6-7 for retention of the device. See page 3 col. 4 of the translation and figures 1-2. It would have been obvious to one of ordinary skill in the art to modify the drainage catheter of

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Yarger with a cuff as taught by Hikedi et al. in order to provide securement and immobilization of the catheter as necessary for an ambulatory patient.

## Response to Arguments

Applicant's arguments filed 04/19/06 have been fully considered but they are moot in view of the new rejection. The Examiner has provided a new rejection in response to applicant's amendment.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000)

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